

**REMARKS**

In restricting the claims, the Examiner states that Group III product claims are related to Group I "method of making" claims. The Examiner relies upon MPEP § 806.05(f), and in particular, upon the rule stating that restriction of product claims and claims directed to making the product may be proper if it can be shown that the product as claimed can be made by another materially different process.

Applicants, in a good faith effort to expedite the prosecution of this application, hereby provisionally elect Group III claims, claims 19-21 and 52, in full, and claims 27-29 and 53, in part, drawn to a cationic nonviral delivery vehicle. Nonetheless, Applicants traverse the Examiner's restriction with respect to the election as more fully set forth below. In particular, Applicants traverse the Examiner's restriction between the Group III claims and the Group I claims (i.e., claims 1-18 in full, and claims 22-26 in part, drawn to methods of making a cationic nonviral delivery vehicle), and Applicants contend herein that the Group III and Group I claims should be examined together, because the Examiner's search of all claims included in Group III and Group I would not impose a serious search burden on the Examiner.

Under the "Guidelines" for restriction requirement practice, the Examiner is required to "provide reasons and/or examples to support conclusions" for the restriction requirement in view of the standard set forth in MPEP 803. The Examiner contends that searching Group I and Group III claims together would impose a serious search burden. Applicants respectfully disagree and traverse the present restriction requirement between Group I and Group III claims, for the following reasons.

In the assertion that the product as claimed can be made by another materially different process, the Examiner alleges that it is routine in the art "to mix pre-made cationic sterol derivatives together with a colipid." The Examiner further alleges that the polyamine and steroid elements need not be combined prior to mixing either the steroid or polyamine element with a lipid. Applicants respectfully contend that the Examiner has mischaracterized the presently-claimed invention, and that the Examiner has misapplied the rule set forth in MPEP § 806.05(f). As a result, it is Applicants' view that the Examiner's restriction of Group III and Group I claims from one another is improper.

Applicants' claimed invention in the method claims of Group I is directed to a specific conjugation of a steroid and polyamine to prepare a first compound prior to combination

of the specifically-conjugated product with a lipid component. That is, Applicants claim the combination of a steroid-polyamine conjugate, the specific combination of which has not been previously disclosed, with a lipid. Therefore, contrary to the Examiner's first allegation that it is routine in the art "to mix pre-made cationic sterol derivatives together with a colipid", the example provided by the Examiner – U.S. Patent No. 5,650,096 – does not provide such evidence, as the steroid-polyamine linkage claimed in the cited patent is counterintuitive to that taught in the present invention.

The Examiner further fails to comply with the rule set forth in MPEP § 806.05(f), because the Examiner provides no evidence to support the assertion that the polyamine and steroid elements need not be combined prior to mixing either the steroid or polyamine element with a lipid. In particular, the Examiner does not provide any showing that the *specific* conjugation of a steroid and polyamine according to the presently-claimed invention can be achieved by a materially different process, e.g., via a process in which the polyamine and steroid elements are not be combined prior to mixing either the steroid or polyamine element with a lipid.

The Examiner has not provided any evidence that the product as claimed can be made by another materially different process, and has therefore not complied with the requirement set forth in MPEP § 806.05(f). Because the Examiner has not satisfied this requirement, the Examiner therefore has not established that a search of the claims of Group III and Group I at this time would impose a serious burden on the Examiner. Such a showing is required under MPEP § 803 to support the Examiner's conclusion.

In conclusion, Applicants traverse the Examiner's restriction of Group III claims and Group I claims on the grounds that the Examiner has not established that a concurrent search of the Group III claims and the Group I claims would provide a serious burden on the Examiner. Applicants therefore respectfully request withdrawal of the restriction as applied to the Group III claims and the Group I claims set forth in the restriction requirement, and request that all claims in Group III and Group I be searched and examined at this time.

Applicants hereby state that no comparison or statement is being made herein regarding novelty or patentability of the Group III claims in view of the Group I claims, or vice versa. Rather, Applicants' instant traversal pertains solely to the search burden imposed upon the Examiner.

Summary

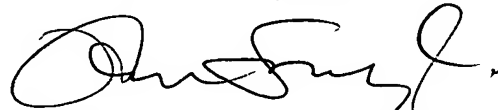
Withdrawal of the restriction as described above and examination of the claims of Group III and Group I on the merits at the earliest possible time is respectfully requested.

Should the Examiner have any questions or comments regarding Applicants' amendments or response, the Examiner is asked to contact Applicants' undersigned representative at (215) 988.2700. Please direct all correspondence to the address listed below.

If there are any additional fees due in connection with the filing of this response, please charge the fees to Deposit Account No. 50-0573.

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Respectfully submitted,  
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